

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: Bair Hugger Forced Air Warming MDL No. 2666 (JNE/FLN)
Products Liability Litigation

This Document Relates to
ALL ACTIONS

**MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
WITH RESPECT TO GENERAL CAUSATION**

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INTRODUCTION

Every one of Plaintiffs' claims requires proof of causation, and that includes proof of general causation that the 3M Bair Hugger™ patient warming system causes surgical infections. Plaintiffs have failed to come forward, as they must, with admissible expert evidence that "rules in" the Bair Hugger system as a cause. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) ("*Glastetter II*") (explaining "rule in," "rule out" framework for medical causation and affirming summary judgment for defendant based on plaintiff's failure to come forward with admissible "rule in" expert testimony); *Wilhelm v. St. Jude Med., Inc.*, No. C4-06-3383, 2007 WL 4792253 (Minn. Dist. Ct. Sept. 10, 2007) (Ramsey County case citing *Glastetter II* and its "rule in," "rule out" framework). Because Plaintiffs cannot establish general causation, all their claims must fail. Accordingly, Defendants respectfully request that the Courts grant summary judgment for Defendants in the federal MDL and the Ramsey County proceedings pursuant to Fed. R. Civ. P. 56 and Minn. R. Civ. P. 56.02, respectively.¹

At bottom, the state of affairs today is just as it was at "Science Day" more than a year ago. Plaintiffs' experts still do not, and cannot, overcome the fact that the scientific literature they rely upon *expressly disclaims* any finding of causation. *See Glastetter II*, 252 F.3d at 990 (8th Cir. 2001) (even medical text that ventured a "hesitant conclusion" on causation was not "scientifically convincing evidence" because "the explanation made

¹ With the permission of the Ramsey County court, this motion and Defendants' motions to exclude Plaintiffs' general causation experts are being filed concurrently in the Ramsey County proceedings. The memoranda address both federal and state legal standards.

clear that more research was needed before causation could be firmly established”); *Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009) (“[I]t is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation has been proved.”). Their attempt to draw conclusions from the literature – and particularly a single uncontrolled observational study (McGovern 2011) – that the literature itself does not support falls far short of the admissibility standards under Eighth Circuit and Minnesota law.

Of additional significance under Minnesota law, which considers whether experts’ theories are “generally accepted,” independent medical authorities such as the ECRI Institute and the Association of periOperative Registered Nurses have consistently rejected the conclusion that the Bair Hugger system causes surgical infections. *See McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. Ct. App. 2004). Just two weeks ago, the FDA reiterated its conclusion that use of forced air warming systems (of which the Bair Hugger system is by far the most widely used type) *reduces* infection risk and provides a host of other benefits to patients. Declaration of Benjamin W. Hulse in Support of Defendants’ Motion to Exclude Plaintiffs’ General Causation Medical Experts (“Hulse Decl.”) DX1, FDA Safety Letter: “Information About the Use of Forced Air Thermal Regulation Systems – Letter to Health Care Providers (Aug. 30, 2017).

This Court and the Ramsey County court do not need to exclude all of Plaintiffs’ experts to grant summary judgment. These are medical injury cases, and medical expertise is required. *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000); *Wilhelm*, 2007 WL 4792253. Plaintiffs’ four engineering experts (only *one* of whom is relied upon

by any of Plaintiffs’ three medical experts) cannot satisfy the burden of proving general causation by themselves. *See Barrett v. Rhodia, Inc.*, 606 F.3d 975, 982-83 (8th Cir. 2010). Accordingly, so long as the Court excludes Plaintiffs’ three medical experts – Dr. Samet, Dr. Jarvis, and Dr. Stonnington – summary judgment is appropriate. *See Glastetter v. Novartis Pharms. Corp.*, 107 F. Supp. 2d 1015, 1016 (E.D. Mo. 2000) (“*Glastetter I*”) (“Having considered the arguments advanced by the parties at the hearing, the Court concludes that defendant is entitled to summary judgment, because plaintiffs’ evidence of causation fails the test for scientific reliability set forth in *Daubert*”); *aff’d*, *Glastetter II*, 252 F.3d 986; *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 957 (D. Minn. 2009) (“*Viagra II*”) (“absent an admissible general causation opinion, Plaintiffs’ claims necessary fail and Pfizer’s motion for summary judgment must be granted”).

BACKGROUND

A. The Bair Hugger System Has a Longstanding Track Record of Safety.

This Court and the Ramsey County court are familiar with the factual background of this litigation, and Defendants therefore restate it only briefly here. There is no dispute that 200 million surgeries have been conducted using the Bair Hugger system over more than 25 years. Plaintiffs have never presented evidence that any doctor has ever reported that the Bair Hugger system caused his or her patient to develop a surgical site infection. Hulse Decl. DX24, *In re 3M Bair Hugger Litig.*, No. 62-CV-15-6432 (Minn. Dist. Ct. – Ramsey County Aug. 18, 2017, Order 10, Memorandum ¶ 28 (hereinafter, “Ramsey County Order 10”). The FDA has never issued any safety communication, warning letter,

or taken any other enforcement action related to an infection purportedly caused by the Bair Hugger system. *Id.* ¶ 27.

B. Surgical Infections Are a Known Surgical Complication with Many Possible Causes Specific to Each Patient.

It is beyond dispute that there are common, scientifically supported causes of surgical infections that have nothing to do with the Bair Hugger system. As the Centers for Disease Control have reported, surgical infections arise from the complex individual circumstances of a patient's surgery, involving bacteria that live on patients' skin around the surgical site, bacteria carried by the blood and living in nearby internal organs, bacteria on the surgical staff, and bacteria carried on contaminated surgical equipment. Hulse Decl. DX19, CDC Guideline for Prevention of Surgical Site Infection at 103 (1999).

C. As the FDA Has Warned, the Scare Campaign by Augustine and Plaintiffs Is Having a Real-World, Negative Impact on Patient Care.

For a decade, a competitor of the Defendants', Dr. Scott Augustine, has been engaged in an attack campaign against the safety of the Bair Hugger system to promote his rival patient warming system, the HotDog. His strategy has involved a relentless hostile marketing campaign as well as coordinating, sponsoring, and directing a slew of "studies," some of which were ultimately published. (Even the authors of those publications were forced to disclaim any conclusion that the Bair Hugger system causes surgical infections. Hulse Decl. DX24, Ramsey County Order 10, ¶ 26.) As a third prong of attack, Augustine partnered with plaintiffs' attorneys to generate litigation that would cast a cloud over the Bair Hugger system. ECF No. 250, Order on Defendants' Motion to Compel Production from Dr. Scott Augustine, at 9 ("There are numerous communications between Augustine

and Kennedy Hodges relating to an initiative by the two in 2013 to publicize the Walton case and to solicit other lawyers to bring similar cases. The documents appear to show that the two drafted a solicitation letter and a ‘litigation guide,’ a portion of which they distributed widely to attorneys who practice personal injury law, collating a large distribution list from a professional organization’s membership list. It appears that their motivation in reaching out was to motivate other attorneys to bring related cases or to refer clients to Kennedy Hodges for its assessment of whether to bring a potential case.”). Both directly, and through a set of entities under his control, Augustine has publicized the litigation widely (alongside the advertising of plaintiffs’ attorneys), to spread fear among doctors and healthcare providers, and turn them away from the Bair Hugger system. *Id.*

This scare campaign has been effective, to a degree. As the FDA recognized in its August 30, 2017 safety communication concerning forced air warming, “some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery).” Hulse Decl. DX1, FDA Safety Alert. Concerned about the “adverse health consequences for patients during the postoperative and recovery process” if doctors and hospitals stopped using patient warming, the FDA “remind[ed] health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.” *Id.* The FDA “collected and analyzed data available” from the published literature and other sources and

was “unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.” *Id.*

This is the backdrop of Defendants’ motions to exclude Plaintiffs’ experts and for summary judgment. In the real world, where patients’ safety is at stake, Augustine and this litigation are deterring doctors and hospitals from using the Bair Hugger system and other forced air warming devices. They are putting patients at risk, and depriving them of the FDA-confirmed benefits of using the Bair Hugger system, including *reduced* infection rates. And they are doing so without the support of *any* scientific study finding that the Bair Hugger system causes surgical site infections.

ARGUMENT

I. THE COURTS SHOULD GRANT SUMMARY JUDGMENT FOR DEFENDANTS BECAUSE PLAINTIFFS LACK ADMISSIBLE MEDICAL EXPERT OPINIONS TO DEMONSTRATE GENERAL CAUSATION.

A. All of Plaintiffs’ Claims Require Proof of Causation.

Dispositive motion practice in this litigation has been bifurcated into two phases. In the present phase, Defendants are moving for summary judgment on the issue of general causation. If Plaintiffs’ claims survive this motion (and they should not), then Defendants will move for summary judgment on bellwether-case-specific issues, which involve either the specific facts of the bellwether plaintiff’s case, or the specific state law that applies to the bellwether plaintiffs’ cases, or both.

There can be no dispute that all of Plaintiffs’ claims, regardless of how they are styled and which state’s law applies, require proof of causation: that is, that the alleged

infection was caused by the Bair Hugger system.² *See, e.g., Viagra II*, 658 F. Supp. 2d at 968 (concluding that proof of general and specific causation is required for all plaintiffs' claims: strict liability in design defect, failure to warn, negligent failure to warn, negligence per se, breach of implied warranty of merchantability and implied warranty of fitness for a particular purpose, breach of express warranty, fraud/misrepresentation, unjust enrichment); *see also Willert v. Ortho Pharm. Corp.*, 995 F. Supp. 979, 983 (D. Minn. 1998) ("An essential element to all of plaintiffs' theories is admissible proof that [the product] caused [plaintiffs' illnesses]."); *Johnson v. Zimmer, Inc.*, No. Civ. 02-1328, 2004 WL 742038, at *6 (D. Minn. Mar. 31, 2004) (citing *J&W Enters., Inc. v. Economy Sales, Inc.*, 486 N.W.2d 179, 181 (Minn. Ct. App. 1991) ("Causation is an indispensable element of [plaintiff's] case, regardless of the theory under which he proceeds.")); *Rients v. Int'l Harvester Co.*, 346 N.W.2d 359, 362 (Minn. Ct. App. 1984) ("In any theory of products liability, the plaintiff must show a causal link between the alleged defect and the injury.").³

² The Master Long Form Complaint and Jury Demand includes the following claims: (1) Negligence, (2) Strict Liability (failure to warn, defective design and manufacture), (3) Breach of Express Warranty, (4) Breach of Implied Warranty, (5) Violation of the Minnesota Prevention of Consumer Fraud Act, (6) Violation of the Minnesota Deceptive Trade Practices Act, (7) Violation of the Minnesota Unlawful Trade Practices Act, (8) Violation of the Minnesota False Advertising Act, (9) Consumer Fraud and/or Unfair and Deceptive Trade Practices Under State Law, (10) Negligent Misrepresentation, (11) Fraudulent Misrepresentation, (12) Fraudulent Concealment, (13) Loss of Consortium, and (14) Unjust Enrichment.

³ The causation requirement is implicit in the elements of Plaintiffs' unjust enrichment claim. Plaintiffs must prove that Defendants received a benefit under circumstances that would make the retention of such benefit unjust. *See, e.g., Cromeans v. Morgan Keegan & Co., Inc.*, 303 F.R.D. 543, 558 (W.D. Mo. 2014) ("While each state in the United States describes unjust enrichment differently, the essence of such claims is that the defendant obtained a benefit, the plaintiff suffered an economic detriment as a result, and it would be

B. Medical Expert Testimony Is Required to Establish Causation.

Under Eighth Circuit law, the cause of medical injuries “requiring surgical intervention or other highly scientific technique for diagnosis . . . is not within the realm of lay understanding and must be established through expert testimony.” *Turner*, 229 F.3d at 1210. To “rule in” the defendant’s product as a cause, plaintiffs must present expert testimony that “demonstrate[s] to an acceptable degree of medical certainty” that the defendant’s product can cause the type of injury the plaintiffs’ allegedly suffered. *Glastetter II*, 252 F.3d at 989. “Without credible expert testimony to prove medical causation, Plaintiffs cannot meet their burden and summary judgment is warranted.” *Willert*, 995 F. Supp. at 983 (granting summary judgment for defendant in pharmaceutical products liability case after the court excluded the testimony of plaintiffs’ expert witness on causation); *see also Medalen v. Tiger Drylac U.S.A., Inc.*, 269 F. Supp. 2d 1118, 1121, 1139-40 (D. Minn. 2003) (granting summary judgment for defendants in product liability action where plaintiffs’ proposed medical expert testimony failed to establish a “submissible showing of causation”).

In a lengthy and thorough recent opinion, the federal district court overseeing the Lipitor MDL also concluded the rule requiring medical expert opinions applies in *every jurisdiction*: “While the specific language used by courts vary to some degree, all

inequitable for the defendant to keep the benefit under the circumstances.”). Because there is no admissible evidence that the Bair Hugger system causes surgical infections, there is no proof that Defendants received any benefit such that it would be *unjust* to permit its retention. *See Viagra II*, 658 F. Supp. 2d at 969 (granting summary judgment for this reason under Minnesota law).

jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 227 F. Supp. 3d 452, 469-77 (D.S.C. 2017) (collecting authorities from all 50 states and the District of Columbia).⁴ Surgical infections are indisputably the kind of complicated injuries with non-obvious causes that must be established through medical expert testimony. *Turner*, 229 F.3d at 1210; *consider also Baycol Prods. Litig.*, 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004) (expert testimony is particularly important in “personal injury cases involving pharmaceuticals, toxins or medical devices” because such cases “involve complex questions of medical causation beyond the understanding of a lay person”). Thus, if Plaintiffs’ medical experts’ opinions on general causation are excluded, Plaintiffs cannot proceed on any of their claims.

C. The General Causation Opinions of Plaintiffs’ Experts Are Inadmissible Under Fed. R. Evid. 702 and *Daubert*.

Only five of the seven experts disclosed by Plaintiffs (Jonathan M. Samet, William Jarvis, Michael J. Stonnington, Yadin David, and Daniel Koenigshofer) offer the opinion that the Bair Hugger system causes surgical infections,⁵ as set forth in the chart below:

⁴ Minnesota law is the same. *See Willert*, 995 F. Supp. at 983 (“Under Minnesota law, ‘[w]here the question involves obscure and abstruse medical factors such that the ordinary layman cannot reasonably possess well-founded knowledge of the matter . . . there must be expert testimony that the thing alleged to have caused the result not only might have done so, but in fact did cause it.’”) (ellipsis in original); *Johnson*, 2004 WL 742038, at *6 (“Under Minnesota law, expert testimony is required to prove causation in cases involving complex medical issues with which a jury is unlikely to have experience.”).

⁵ Plaintiffs’ two other experts (Buck and Elghobashi) limit their opinions to the purported effect of the Bair Hugger system on airborne particles; they stop short of opining that the device causes or increases the risk of infections. Only Elghobashi’s modeling is relied

Plaintiffs' Expert	General Causation Opinion
Samet	<p>“The Bair Hugger device is not a necessary cause, but a causal factor that increases risk of deep joint infection by adding an additional causal mechanism.” (Hulse Dec. DX2, Samet Rpt. at 17.)</p> <p>Based on the elevated odds ratio of 3.8 in the McGovern study, “the Bair Hugger device would constitute a substantial contributing cause.” (<i>Id.</i>)</p>
Jarvis	<p>“[B]ased on the report of Dr. Said Elghobashi's detailed and impressive LES simulation analysis, together with the published peer-review literature showing that the Bair Hugger FAWs increase particulates in the OR, it is my opinion, to a reasonable degree of medical certainty, that the Bair Hugger FAW more likely than not is a substantial contributing factor in the causation of PJIs.” (Hulse Decl. DX4, Jarvis Rpt. at 24-25.)</p>
Stonnington	<p>“[I]t is my expert opinion to a reasonable degree of scientific probability, that the Bair Hugger system causes an increased risk of patient infection because of substantial scientific evidence that the waste heat generated by the Bair Hugger warming units disrupts operating room airflow conditions and contributes to mobilization of microbes in the area of the sterile field.” (Hulse Decl. DX6, Stonnington Rpt. at 7.)</p>
David	<p>“[The Bair Hugger system's] design and marketing were unreasonably dangerous because the devices are more likely than not contributing to infections during orthopedic implant surgeries.” (ECF No. 316, David Rpt. at 1.)</p>
Koenigshofer	<p>“In summary, I believe that use of the Bair Hugger will adversely affect the air quality in the OR and at the</p>

upon by other experts (specifically, Samet and Jarvis). The reports of Buck and Koenigshofer are not cited by any of Plaintiffs' other experts.

	patient. This will place the patient at increased risk of contracting an HAI [hospital associated infection].” (Goss Decl. DX35, Koenigshofer Rpt. at 23.)
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These experts’ opinions are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

The opinions of Plaintiffs’ three medical doctor experts (Drs. Samet, Jarvis, and Stonnington) are inadmissible for the reasons discussed in Defendants’ Motion to Exclude Plaintiffs’ General Causation Medical Experts. These reasons are discussed briefly here. All three depend on a single uncontrolled observational study (the McGovern study) to support their opinions that the Bair Hugger system increases the incidence of surgical site infections. They concede that, without the McGovern study, they would have no ability to quantify the alleged risk. Hulse Decl. DX3, Samet Dep. at 283:16-20. But the McGovern study itself is entirely unreliable, for several reasons.

First, the authors of the McGovern study expressly disclaimed any finding that the Bair Hugger system causes surgical site infections. *See Huss*, 571 F.3d at 442 (“[I]t is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation has been proved.”).

Second, confounding factors disclosed in the McGovern study account entirely for the purported association between Bair Hugger use and increased infections. These include a change in drug regimen midway through the study. As the study’s co-author and chief number-cruncher, Mark Albrecht, conceded in his deposition, there was no statistically

significant increase in infection rates when the change in drug regimen is accounted for. Yet, contrary to sound medical science, Plaintiffs' experts ignored this critical confounding factor and Mr. Albrecht's testimony. See Federal Judicial Center, *Reference Manual on Scientific Evidence* 598 (3d ed. 2011) ("In assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors . . ."); *id.* at 612 (noting that the propriety of using epidemiology to infer causation depends upon evaluating whether confounding factors are the source of the association); see also *General Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (1997) (finding that a study which failed to control for other factors that may have caused plaintiff's cancer did not reliably support the expert's opinion).

Third, as another co-author testified, there were major undisclosed confounders that affected the study. The hospital implemented a massive initiative to bring down infection rates, but the infection-control measures were implemented prior to the period where the competitor patient warming system (Augustine's HotDog) was being used, and thus the HotDog patients had the benefit of multiple infection control measures that the Bair Hugger patients did not). Though these confounding factors were obvious from discovery materials in the case (namely, the deposition of study co-author Michael Reed), Samet, Jarvis, and Stonnington failed entirely to consider these confounders in their opinions.

Fourth, Defendants' expert Prof. Theodore Holford has demonstrated, based on their review of the data underlying the McGovern study, that it suffers from major tabulation errors. When these tabulation errors are corrected, the association between Bair Hugger use and increased infections disappears. Plaintiffs' experts do not dispute Prof.

Holford's reanalysis of the data. Hulse Decl. DX3, Samet Dep. at 126:3-7 ("Oh, he [Holford] certainly did the calculations correctly.").

And *fifth*, the McGovern study purports to compare infection rates between the Bair Hugger system and Augustine's HotDog – it does not compare the Bair Hugger system against background risk to the general population of orthopedic patients (that is, patients who are not warmed). See *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1247-48 (11th Cir. 2005) ("A reliable methodology should take into account the background risk.").

Because the McGovern study is not scientifically compelling evidence supporting their general causation opinions, Plaintiffs' medical experts must be excluded. See *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 936, 944-45 (D. Minn. 2009) ("*Viagra I*") (concluding that epidemiological study relied upon by plaintiffs' expert was not reliable, despite being published and peer-reviewed, because plaintiffs failed to rebut miscodings and errors identified by defendants). Moreover, even if they did have scientifically compelling evidence to support their opinion that the Bair Hugger system causes surgical site infections, they offer no methodology whatsoever for reliably ruling out the far more likely causes, such as bacteria on the plaintiff's own skin around the surgical site, bacteria carried by the blood and living in nearby internal organs, bacteria on the surgical staff, and bacteria carried on contaminated surgical equipment.

The opinions of Dr. David and Mr. Koenigshofer, the two engineering experts who give general causation opinions, are also inadmissible, for clear-cut reasons. As explained in Defendants' concurrently filed motions, neither David nor Koenigshofer is qualified to opine on whether the Bair Hugger system causes surgical site infections "to an acceptable

degree of medical certainty.” *Glastetter II*, 252 F.3d at 989. They are engineers, not medical doctors, and have no expertise in epidemiology, biostatistics, infectious disease, or any field of medical science. In his professional work relating to helping his hospital make purchasing decisions, David relies on physicians and nurses to evaluate risk. Because Dr. David does not evaluate clinical risks on his own in his professional capacity, he is unqualified to do so in litigation. *Barrett*, 606 F.3d at 982-83 (affirming exclusion of engineering expert whose opinion included pinpointing the cause of the plaintiff’s injury). The same is true for Mr. Koenigshofer.

D. The Opinions of Plaintiffs’ Engineering Experts Are Inadmissible for Several Additional Reasons.

The opinions of Plaintiffs’ engineering experts (Buck, David, Elghobashi, and Koenigshofer) are inadmissible for several other reasons, as discussed in Defendants’ motions to exclude their testimony. For example, their opinions depend on the deeply flawed “research” conducted by and on behalf of Dr. Scott Augustine and his cohorts—all of which *still* disclaims any finding of causation. Further, it is not enough for Plaintiffs’ engineering experts simply to propose hypothetical mechanisms by which the Bair Hugger system, in theory, might increase the risk of infection. They must demonstrate, based on scientifically convincing evidence, that that their proposed mechanisms actually *do* increase the risk of infection in the real world. *Glastetter II*, 252 F.3d at 989 (plaintiffs must provide “*scientifically convincing evidence*” to “demonstrate[] [general causation] to an acceptable degree of *medical certainty*” (emphasis added)). Yet Plaintiffs’ engineering experts never conducted any tests to determine whether use of the Bair Hugger causes an

increase in *bacteria* at the surgical site. Likewise, none of the Augustine-sponsored papers on which Plaintiffs’ engineering experts rely shows an increase in bacteria during Bair Hugger system use. Thus, Plaintiffs’ engineering experts’ testimony about the Bair Hugger “harboring” bacteria and influencing airflow is nothing more than speculation. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 431 (S.D.N.Y. 2016) (“Indeed, the courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags science; it does not lead it.” (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996))); *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1296 (M.D. Fla. 2007) (“While [the expert’s] biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation. . . . Without verification, [the expert’s] theory remains an educated guess.”); *In re Bausch & Lomb, Inc. Contact Lens Solution Prods. Liab. Litig.*, MDL No. 1785, 2009 WL 2750462, at *12 (D.S.C. Aug. 26, 2009) (same). And to the contrary, as has been demonstrated through discovery, the Augustine researchers tried on multiple occasions to demonstrate an increase in bacteria from use of the Bair Hugger system, and found none. These studies were kept secret. Moreover, published studies have consistently found—as Augustine’s researchers did—that use of the Bair Hugger does not increase bacteria in the operating room or at the surgical site. *See Glastetter I*, 107 F. Supp. 2d at 1032-35; *Glastetter II*, 252 F.3d at 990.

In sum, because Plaintiffs have presented no expert opinions that reliably “rule in” the Bair Hugger system as a cause of their alleged infections, they cannot prove causation under the law of any state and summary judgment is appropriate. *See Glastetter I*, 107 F. Supp. 2d at 1045 (“[I]n the absence of any scientifically valid evidence supporting

plaintiffs' theory of causation, defendant is entitled to summary judgment as well."); *aff'd*, *Glastetter II*, 252 F.3d at 992.

II. SUMMARY JUDGMENT IS ALSO APPROPRIATE UNDER MINNESOTA LAW BECAUSE PLAINTIFFS' EXPERTS' THEORIES ARE NOT ACCEPTED BY THE MEDICAL COMMUNITY.

Summary judgment is also appropriate under Minnesota law because Plaintiffs' experts' general causation opinions do not satisfy the *Frye-Mack* standard for admissibility.⁶ As already discussed, Plaintiffs' experts do not employ reliable principles and methodology or rely upon scientifically convincing evidence that the Bair Hugger system causes surgical infections in the real world. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000) (outlining *Frye-Mack* standard); *Wilhelm*, 2007 WL 4792253 (Ramsey County case citing *Glastetter II*). Their theories, at bottom, are merely conjecture that a causal relationship exists. *See Saaf v. Duluth Police Pension Relief Assn. Minn.*, 59 N.W.2d 883, 886 (Minn. 1953) ("Where expert testimony must be solely relied on to show the causal connection between the alleged cause and a certain subsequent result . . . medical testimony which does nothing more than show a mere possibility, suspicion, or conjecture

⁶ Pursuant to Rule 115.03(d) of the Minnesota Rules of Practice for District Courts, the record supporting this motion is comprised of the Declaration of Benjamin W. Hulse in Support of Defendants' Motion to Exclude Plaintiffs' General Causation Medical Experts, the Declaration of Peter J. Goss in Support of Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Engineering Experts, the Declaration of M. Joseph Winebrenner in Support of Defendants' Motion to Exclude Plaintiffs' Expert Dr. Yadin David, exhibits to those declarations, and all prior proceedings and pleadings before the Courts. The issue is whether Defendants are entitled to judgment as a matter of law due to Plaintiffs' failure to present admissible expert testimony supporting their allegations that the Bair Hugger system causes surgical infections. The undisputed material facts supporting Defendants' motion are set forth in this memorandum and the concurrently filed memoranda in support of Defendants' motions to exclude Plaintiffs' experts.

than [sic] such causal relation exists, without any foundation for the exclusion of other admittedly possible causes, provides no proper foundation for a finding of a causal connection.”).

In addition, under Minnesota law, a scientific theory is not admissible unless the proponent demonstrates that it is generally accepted in the applicable medical or scientific community. *See id.*; *see also McDonough*, 685 N.W.2d at 696 (affirming district court’s determination that plaintiff’s expert’s general causation theory is not generally accepted); It is beyond dispute that the general causation opinions of Plaintiffs’ experts are not generally accepted. Their opinions go far beyond the conclusions of the studies they rely upon, and are at odds with the conclusions of all respected independent authorities who have looked at the issue. There are just some of the examples:

(1) An independent review in 2013 by the Association of periOperative Registered Nurses (AORN) concluded: “Our review uncovered no conclusive evidence that the use of forced-air warmers increases the risk of SSI The evidence also does not support the concern that use of a forced-air warmer may cause an increase in bacteria near or on the patient or cause unwanted airflow disturbances. These findings confirm the AORN recommendations that forced-air warming is an effective way to prevent unplanned perioperative hypothermia.” Hulse Decl. DX16, Kellam M.D. et al., “Forced-air warming devices and the risk of surgical site infections.” 98.4 *AORN Journal* 353, 365-66 (2013).

(2) Also, in 2013, the ECRI Institute, a widely respected nonprofit organization that advises more than 5,000 healthcare organizations, reviewed over 180 studies, including McGovern. ECRI concluded: “we do not believe that the currently available evidence

justifies discontinuing the use of FAW [forced air warming] during surgery.” Hulse Decl. DX15, ECRI Institute, “Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice.” *Health Devices* 122, 122 (April 2013).

(3) Another independent review of the scientific literature (including McGovern and the other seven Augustine papers) by Sikka and Prielipp in the *Journal of Bone & Joint Surgery* concluded in 2014 that “the literature appears to indicate that forced air warming can impact laminar flow under certain very specific conditions, but any actual clinical impact on surgical site infections must be considered unproven at this time.” Hulse Decl. DX17, Sikka R.S., et al., “Forced Air Warming Devices in Orthopaedics: A Focused Review of the Literature,” 96-A:24 *J. Bone & Joint Surgery* e200 (2014).

(4) The 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection, which involved more than 400 experts in musculoskeletal infection from 52 countries, reached a “strong consensus” statement as follows: “We recognize the theoretical risk posed by FAW [forced air warming] blankets and that no studies have shown an increase in SSI [surgical site infections] related to the use of these devices. We recommend further study but no change to current practice.” Hulse Decl. DX18, Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection at 5 (2013). ***Eighty-nine percent*** of delegates voted in support of the statement while only five percent voted against and six percent had no opinion. The discussion and notes indicate that the delegates considered and evaluated the same studies relied upon by SJS, including the McGovern study. *Id.* n.76.

(5) In 2015, Duke University School of Medicine’s Infection Control Outreach Network (DICON) reviewed the literature and found that “no adequately powered, properly controlled, statistically significant, reproducible study has been published that demonstrates an increased risk of SSI due to the use of FAW [forced air warming] warming devices.” DX22, “HotDogs, Bair Huggers, and Lawsuits, Oh My! A brief review of the controversy surrounding perioperative warming methods,” DICON Infection Prevention News (Nov. 2015). DICON strongly criticized the McGovern study, including its failure to account for comorbidities, and noted that “no studies performed by independent investigators” had corroborated its findings. *Id.*⁷

(6) Finally, as discussed above, the FDA recently issued a public letter to healthcare providers concerning patient warming devices, after it became aware that “some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery).” DX1, FDA Safety Alert. The FDA noted that it had conducted “a thorough review of available data,” but “has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.” *Id.* Thus, the agency made clear that it “continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems [of which the Bair Hugger is the most widely used]) for surgical

⁷ See also Hulse Decl. DX23, Allen M.W. et al., “Normothermia in Arthroplasty,” 32:7 *J. Arthroplasty* 2307, 2312 (July 2017) (“Despite recent controversy about forced air warming devices, the literature does not support to an increased risk for infection with such technologies.”).

procedures when clinically warranted. Surgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the postoperative and recovery process.” *Id.* The FDA further reiterated the benefits of forced air warming: “The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and *decreased risk of infection for patients.*” *Id.* (emphasis added).

In sum, medical professionals and regulators who have reviewed the evidence outside the context of litigation do not reach the same conclusions that SJS have reached as paid litigation experts. For this additional reason, Plaintiffs’ experts’ general causation opinions are inadmissible under Minnesota law, and summary judgment is warranted.

CONCLUSION

For all the foregoing reasons, Defendants respectfully request that this Court and the Ramsey County Court grant summary judgment in their favor on the claims of all plaintiffs pending in the MDL and in Ramsey County.

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